CB TEST CERTIFICATE

Ref. Certificate No.
SG-2499M2

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

Issued by:	TÜV SÜD PSB Pte Ltd
Product:	LCD Monitor

Applicant:	DIVA Laboratories Ltd.	7TH FL-8, 351 CHUNG SHAN RD, SEC 2, CHUNG HO, TAIPEI HSIEN 235 TAIWAN	Taiwan
Manufacturer:	DIVA Laboratories Ltd.	7TH FL-8, 351 CHUNG SHAN RD, SEC 2, CHUNG HO, TAIPEI HSIEN 235 TAIWAN	Taiwan
Factory: nb: Additional factory information on page 2	DIVA Laboratories Ltd.	7TH FL-8, 351 CHUNG SHAN RD, SEC 2, CHUNG HO, TAIPEI HSIEN 235 TAIWAN	Taiwan

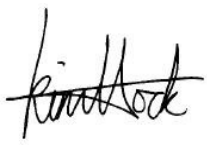
Rating and principal characteristics:	100-240V~, 50/60Hz, 1.2-0.6A, Class I
Trade mark (if any):	DIVA
Model/Type reference:	GODx7yzMI and GOKx7yzMI (where x = 8 or 9, y = 0-9 or A-Z and z = A-Z)
Additional information:	Certificate SG-2499 issued 2006-08-07 and Certificate SG-2499M1 issued 2006-10-25 are replaced by this version due to add model, trademark, alternate metal enclosure and base and alternate classification according to the degree of protection against ingress of water.
Sample of product tested to be in conformity with IEC:	60601-1(ed.2);am1;am2
Test Report Ref. No:	55S072147/NCH/CZ

This CB Test Certificate is issued by the National Certification Body:

TÜV SÜD PSB Pte Ltd
1 Science Park Drive, Singapore 118221

Signed by: Teo Kim Hock

Date of issue: 2007-11-26



LUXON Systems Corporation
No. 161, Hsing Jen Road, Tamshui Taipei Hsien,
Taiwan

Additional information (if necessary)

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TÜV SÜD PSB Pte Ltd
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Signed by: Teo Kim Hock

Date of issue: 2007-11-26

TEST REPORT IEC 601 -1 Medical electrical equipment Part 1: General requirements for safety	
Report reference No. ..... :	55S072147/NCH/CZ
Compiled by (+ signature) ..... :	Ng Chin Heng .....
Reviewed by (+ signature) ..... :	Chen Zhuo .....
Approved by (+ signature) ..... :	Michelle Ng .....
Date of issue ..... :	20 November 2007
Testing laboratory ..... :	TÜV SÜD PSB Pte Ltd
Address ..... :	1 Science Park Drive, Singapore 118221
Testing location ..... :	CBTL ☒ CCATL ☐ SMT ☐ TMP ☐
Applicant ..... :	DIVA Laboratories Ltd.
Address ..... :	7TH FL-8, 351 CHUNG SHAN RD, SEC 2, CHUNG HO, TAIPEI HSIEN 235 TAIWAN
Standard ..... :	IEC 60601-1:1988 + A1:1991 + A2:1995
Test Report Form No. ..... :	I601-1_C/97-04
TRF Originator ..... :	Underwriters Laboratories Inc.
Master TRF ..... :	dated 97-04
Copyright blank test report ..... :	the bodies participating in the Committee of Certification Bodies (CCB). This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator.
Test procedure ..... :	CB Scheme
Procedure deviation ..... :	N/A
Non-standard test method ..... :	N/A
Type of test object ..... :	LCD Monitor
Trademark ..... :	1) DIVA, 2) AG neovo
Model/type reference ..... :	1) GODx7yzMI, GOKx7yzMI, 2) ER-191
Manufacturer ..... :	DIVA Laboratories Ltd.
Address ..... :	7TH FL-8, 351 CHUNG SHAN RD, SEC 2, CHUNG HO, TAIPEI HSIEN 235 TAIWAN
Rating ..... :	100-240 V~, 1.2-0.6 A, 50/60 Hz

Copy of marking plate:

See Appendix 14 to 19 of Test Report Ref. No.: 55S061674/NCH/CZ, Appendix 5 of Test Report Ref. No.: 55S062158/NCH/CZ and Appendix 5 of this Test Report.

GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use ..... :	Portable
Supply connection ..... :	Appliance coupler
Accessories and detachables parts included in the evaluation ..... :	None
Options included ..... :	None
Possible test case verdicts:	
- test case does not apply to the test object ..... :N / A	N
- test object does meet the requirement ..... :Pass	P
- test object does not meet the requirement ..... :Fail	F
Abbreviations used in the report:	
- normal condition ..... :N.C.	- single fault condition .....:S.F.C.
- operational insulation ..... :OP	- basic insulation .....:BI
- basic insulation between parts of opposite polarity ..... :BOP	- supplementary insulation .....:SI
- double insulation ..... :DI	- reinforced insulation.....:RI

General remarks:

"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IECEE 02".

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Summary of contents provided on the last page of this report.

General product information and considerations:

Remark 1: This modify report is to supplement the earlier reports:

- Test Report No. 55S061674/NCH/CZ, dated 31 July 2006 (CB Ref. Certificate No.: SG-2499).
- Test Report No. 55S062158/NCH/CZ, dated 19 October 2006 (CB Ref. Certificate No.: SG-2499M1)

Remark 2: The modifications made on this report were as below:

1. Add model: ER-191.
2. Add Trademark: AG neovo (for model: ER-191)
3. Add alternate metal enclosure and base.
4. Add alternate classification according to the degree of protection against ingress of water: IPX2 (only for model: ER-191).

Remark 3: Model: GOKx7yzMI is identical to Model: GODx7yzMI except for the model designation.
Model: ER-191 is similar to models: GOKx7yzMI & GODx7yzMI except for model designation , enclosure and base.
(Refer to Appendix 6 for the identity declaration letter)
x = 8 for 18" TFT panel size, x = 9 for 19" TFT panel size,
y = 0-9 or A-Z for different sale-area and different customers,
z = A-Z for different TFT panel supplier.

Remark 4: Components used for each model are as below:

Model Description	Components		Trademark
	TFT Panel	DC/AC Inverter	
GOD971FMI GOK971FMI	Sharp / LQ190E1LW41 (Fujitsu / FLC48SXC8V-12)	TDK / TBD319LF-1 Hwa Youn / QF171V1	DIVA
GOD97yFMI GOK97yFMI	Sharp / LQ190E1LW01 (Fujitsu / FLC488XC8V-11)	Hwa Youn / QF74V5	
GOD97yAMI GOK97yAMI	AUO / M190EG01	Hwa Youn / QF74V5	
GOD97yLMI GOK97yLMI	LG / LM190E05	Hwa Youn / QF74V5	
GOD870IMI GOK870IMI	ID Tech / ITSX98E	Ambit / 25L7623	
GOD875IMI GOK875IMI	ID Tech / ITSX88E	Ambit / 25L7623	
GOD971NMI GOK971NMI	NEC / NL128102BC29	TDK / TBD319LF-2	
ER-191	NEC / NL128102BC29	TDK / TBD319LF-2	AG neovo

Remark 5: All tests were conducted on Model: ER-191 unless otherwise specified and is the representative of the other models.

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
5	CLASSIFICATION		P
5.1	Type of protection against electric shock		P
	Class I equipment	Class I equipment.	P
	Class II equipment	Class I equipment.	N
	Internally powered equipment	Class I equipment.	N
5.2	Degree of protection against electric shock		N
	Type B applied part	No applied part.	N
	Type BF applied part		N
	Type CF applied part		N
	Not classified - no applied parts	As the equipment is not intended to be connected to the patient and does not have any patient applied parts, it is should not be marked with the type B applied part symbol. Nevertheless, the product complies with the requirements for type B applied part concerning protection against electric shock.	P
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)..... :	IPX2, only for model: ER-191. (see separate test report)	P
5.4	Methods of sterilization or desinfection	Not applicable.	N
5.5	Equipment not suitable for use in the presence of flammable mixtures	The equipment is not AP or APG category equipment.	N
	Category AP equipment		N
	Category APG equipment		N
5.6	Mode of operation:		P
	-continuous operation	Continuous operation.	P
	-short-time operation, specified operation; period... :		—
	-intermittent operation, specified operation; rest period ..... :		—
	-continuous operation with short-time, stated permissible loading time..... :		—
	-continuous operation with intermittent, stated permissible loading/rest time..... :		—

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

6	Identification, marking and documents		P
6.1	Marking on the outside of equipment or equipment parts		P
	c) Markings of the specific power supply affixed	No applicable. No specific power supply affixed.	N
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	Not applicable.	N
	e) Name and/or trademark of the manufacturer or supplier .....:	DIVA Laboratories Ltd. or DIVA	P
	f) Model or type reference .....:	GODx7yzMI, GOKx7yzMI. ER-191 (see Remark 4 on page 4)	P
	g) Rated supply voltages or voltage range(s)	100-240 V~	P
	Number of phases.....:	Single phase.	N
	Type of current .....:	AC	P
	h) Rated frequency or rated frequency range(s) (Hz) .....:	50/60 Hz	P
	j) Rated power input (VA, W or A).....:	1.2-0.6 A	P
	k) Power output of auxiliary mains socket-outlets	No socket-outlet.	N
	l) Class II symbol	Class I equipment.	N
	Symbol for degree of protection against ingress of water provided .....:	IPX2, wording in manual.	P
	Symbol for protection against electric shock .....:	No applied part.	N
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N
	Symbol for protection of defibrillation-proof applied parts	No defibrillation applied parts.	N
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N
	m) Mode of operation (if no marking, suitable for continuous operation)	Continuous operation.	N
	n) Types and rating of external accessible fuses ....:	No external fuses.	N
	p) Ratings of external output.....:	Not applicable.	N
	q) Symbol for physiological effect(s):		N
	- attention, consult accompanying documents	Symbol 14 of Table DI was used in the User Manual.	P

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N
	r) Anaesthetic-proof symbol: AP or APG .....:	Not of category AP or APG.	N
	s) Dangerous voltage symbol	No accessible high voltage terminal devices.	N
	t) Special cooling requirements	No such devices.	N
	u) Limited mechanical stability	The equipment did no overbalance.	P
	v) Protective packing requirement(s)	No special measure was taken during transportation or storage.	N
	- Marking(s) for unpacking safety hazard(s)		N
	- Equipment or accessories supplied sterile, marked as sterile		N
	y) Potential equalization terminal		N
	- Functional earth terminal		N
	z) Removable protective means	No such devices.	N
	Durability of marking test		P
6.2	Marking on the inside of equipment or equipment parts		P
	a) Nominal voltage of permanently installed equipment	Not permanently connected equipment.	N
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements or lamps inside the equipment.	N
	c) Dangerous voltage symbol	Provided on the inverter, located inside the equipment.	P
	d) Type of battery and mode of insertion	No battery inside the equipment.	N
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		N
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	Fuses were not accessible.	N
	f) Protective earth terminal	Appliance inlet used.	P
	g) Functional earth terminal	No functional earth terminal.	N
	h) Supply neutral conductor in permanently installed equipment (N)	Not permanently installed equipment.	N
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed		N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- Markings comply with IEC 445	See below.	P
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	Not permanently connected equipment.	N
	l) Statement for suitable wiring materials at temperatures over 75 °C	Not permanently connected equipment.	N
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c	No such devices.	N
6.3	Marking of controls and instruments		P
	a) Mains switch clearly identified	See below.	P
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	The line "**I**" for "ON" and circle "**O**" for OFF were provided according to IEC 60417-1-IEC-5007 and 60417-1-IEC-5008.	P
	b) Indication of different positions of control devices and switches	Indication of control devices were provided on the equipment.	P
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device		N
	f) The functions of operator controls and indicators are identified	Provided in the user manual.	P
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2	Provided in SI units.	P
6.4	Symbols		P
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	The line "**I**" for "ON" and circle "**O**" for OFF for mains switch were provided according to IEC 60417-1-IEC-5007 and 60417-1-IEC-5008.	P
6.5	Colors of the insulation of conductors		P
	a) Protective earth conductor has green/yellow insulation	The protective earth conductor is green/yellow color insulation.	P
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		P
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		P
	d) Color of neutral conductor.....:	Not provided with the power supply cord.	N
	e) Colors of phase conductor(s) .....:	Not provided with the power supply cord.	N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- Compliance with IEC 227 and IEC 245		N
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors	Multi-conductor cord not used.	N
6.6	Medical gas cylinders and connections		N
	a) In accordance with ISO ISO/R 32	No such device.	N
	b) Identification of connection point		N
6.7	Indicator lights and push-buttons		N
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	No red indicator or light used.	N
	- Yellow used to indicate caution or attention required		N
	- Yellow used to indicate caution or attention required		N
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency		N
6.8	ACCOMPANYING DOCUMENTS		P
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Provided in the user manual.	P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	Provided in the user manual.	P
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Provided on the equipment.	N
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Provided in the user manual.	P
6.8.2	Instructions for use		P
	a) General information provided in instructions for use	Provided in the user manual.	P
	- state the function and intended application of the equipment	Provided in the user manual.	P
	- include an explanation of: the function of controls, displays and signals	Provided in the user manual.	P
	- the sequence of operation	Provided in the user manual.	P
	- the connection and disconnection of detachable parts and accessories	Provided in the user manual.	P

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- the replacement of material which is consumed during operation	No replacement material.	N
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Provided in the user manual.	P
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		N
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Provided in the user manual.	P
	General information provided in instructions:		P
	- information for the safe performance or routine maintenance	Routine maintenance is not necessary.	N
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	Preventive inspection and maintenance are not necessary.	N
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	Provided in the user manual.	P
	c) Signal output or signal input parts intended only for connection to specified equipment described	Provided in the user manual.	P
	d) Details about acceptable cleaning, disinfection or sterilization methods included	No direct contact to the patient.	N
	e) Warning statement for mains operated equipment with additional power source	No additional power source.	N
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	No battery inside the equipment.	N
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	No battery inside the equipment.	N
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	No such device.	N
	j) Identification of any risks associated with the disposal of waste products, residues, etc.		N
	- Advice in minimizing these risks		N
6.8.3	Technical description		P
	a) All characteristics essential for safe operation provided	Provided in the user manual.	P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	Not permanently connected equipment.	N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	No such device.	N
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	No user repairable parts.	N
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Temperature: -20°C to +60°C Humidity: 10% to 90%RH Air Pressure: 187 to 1060hPa	P
16	**ENCLOSURES AND PROTECTIVE COVERS**		P
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	In compliance with the leakage current requirements. (see appended table)	P
	Insertion or removal of lamps - protection against contact with live parts provided	No lamps inside the equipment.	N
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	Components enclosed in the EUT cannot be touched by the test rod.	P
16c	Conductive parts accessible after the removal of handles, knobs, levers		N
	- have a resistance of not more than 0.2 Ω	No such parts.	N
	- separated from live parts by one of the means described in Sub-clause 17g		N
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact	No accessible internal components	N
16e	Removable enclosures protecting against contact with live parts.		P
	- Removal possible only with the aid of a tool	The removal of the enclosure needs the aid of tool.	P
	- Use of automatic device making parts not live when the enclosure is opened or removed		N
	- Exception 16e applied to the following parts .....:		N
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No pre-set control which may be adjusted during normal used.	N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

18	**PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION**		P
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		P
18b	Protective earth terminals suitable for connection to the protective earth conductor	Appliance inlet used.	P
18e	Potential equalization conductor		N
	- Readily accessible	No connection to potential equalization conductor.	N
	- Accidental disconnection prevented in normal use		N
	- Conductor detachable without the use of a tool		N
	- Power supply cord does not incorporate a potential equalization conductor		N
	- Connection means marked with Symbol 9, Table DI		N
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1\ \Omega$		N
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1\ \Omega$	(See appended table18)	P
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2\ \Omega$		N
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1 Ω, the allowable value of the enclosure leakage current is not exceeded in single fault condition		N
18k	Functional earth terminal not used to provide protective earthing	Functional earthing terminal not used.	N
18l	Class II equipment with isolated internal screens		N
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N
	- functional earth terminal clearly marked		N
	- explanation of functional earth terminal provided in the accompanying documents		N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
19	**CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS**		P
19.1b	Leakage currents	(see appended table 19)	P
	- earth leakage current		P
	- enclosure leakage current		P
	- patient leakage current	No patient leakage current.	N
	- patient auxiliary current	No patient auxiliary current.	N
20	**DIELECTRIC STRENGTH**		P
	Overall compliance with Clause 20	(see appended table 20)	P
21	**MECHANICAL STRENGTH**		P
21a	Sufficient rigidity of an enclosure tested by: force of 45 N	(see appended table 21)	P
21b	Sufficient strength of an enclosure tested by: impact hammer	No damage after the test.	P
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test	No handle and grip on the enclosure.	N
21.3	No damage to parts of patient support and/or immobilization system after the loading test	No such parts.	N
21.5	Hand held equipment or equipment parts are safe after drop test	No hand held equipment.	N
21.6	Portable and mobile equipment is able to withstand rough handling	(see appended table 21)	P

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

24	**STABILITY IN NORMAL USE (SEE APPENDED TABLE 24)**		P
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10º	The EUT did not overbalance at 10º.	P
24.3	Equipment overbalances when tilted through an angle of 10º		N
	- does not overbalance when tilted through an angle of 5º in any position excluding transport		N
	- carry a warning notice stating that transport should only be undertaken in a certain position		N
	- in the position specified for transport does not overbalance when tilted to an angle of 10º		N
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		N
	- suitable handling devices (grips etc.), or	The weight of the equipment, ER-191 is 8.2 kg. (< 20 kg)	N
	- instructions for lifting and handling during assembly		N
24.6b	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		N

42	**EXCESSIVE TEMPERATURES**		P
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	(see appended table 42)	P
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25ºC ambient	(see appended table 42)	P
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41ºC		N
42.5	Guards to prevent contact with hot surfaces removable only with a tool	No such surface.	N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

44	**OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION**		P
44.2	Equipment contain a liquid reservoir:		N
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	No liquid reservoir inside the equipment.	N
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15º in the least favorable direction(s) (if necessary with refilling)		N
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)	No use of liquid inside the equipment.	N
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N
44.5	Equipment sufficiently protected against the effects of humidity	30ºC, 168 hours, 93% RH. (See appended table)	P
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	IPX2, only for model: ER-191. (see separate test report)	P
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	Testing performed according to method described in the user manual.	P

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

52	**ABNORMAL OPERATION AND FAULT CONDITIONS**		P
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	(see appended table 52)	P
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4		N
52.5.2	Failure of thermostats presents no safety hazards	No thermostat used.	N
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard		N
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5ºC		P
52.5.6	Locking of moving parts presents no safety hazard	No moving part inside the equipment.	N
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No motor inside the equipment.	N
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8	No motor used.	N
52.5.9	Failure of one component at a time presents no safety hazard	(see appended table 52)	P
52.5.10	Overload of heating elements presents no safety hazard	No heating elements.	N
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N
	h) Equipment with three-phase motors can safely operate with one phase disconnected	No motor inside the equipment.	N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

56	**COMPONENTS AND GENERAL ASSEMBLY**		P
	List of critical components	(see appended table 56.1)	P
56.1b	Ratings of components not in conflict with the conditions of use in equipment	The components are used according to their rating.	P
	Ratings of mains components are identified	The critical components were used within the intended rating.	P
56.1d	Components, movements of which could result in a safety hazard mounted securely	The movement of components is prevented.	P
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	No connection was likely to be detached.	P
56.3a	Connectors provide separation required by Sub-clause 17g	Double or reinforce insulation provided.	P
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No connection to the patient.	N
	Medical gas connections not interchangeable		N
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	Interconnection cord only connected to Safety Extra Low Voltage.	P
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	No patient connection.	N
56.4	Connections of capacitors		P
	Not connected between live parts and non-protectively earthed accessible parts		P
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14	Evaluated in the certified power supply.	P
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts	No such device.	N
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs	No thermal cut-off used.	N
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	No such device.	N
56.6	Temperature and overload control devices		N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment	No thermal cut-out inside the equipment.	N
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	No thermal safety devices inside the equipment.	N
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	No such device.	N
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times	No such device.	N
	Non-self resetting over-current releases operated 10 times		N
56.6b	Thermostats with varying temperature settings clearly indicated	No thermostat inside the equipment.	N
	Operating temperature of thermal cut-outs indicated		N
56.7	Batteries		N
	a) Battery compartments:		N
	- adequately ventilated	No battery inside the equipment.	N
	- accidentally short-circuiting is prevented		N
	b) Incorrect polarity of connection prevented		N
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		P
	- to indicate that equipment is energized		N
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No heaters inside the equipment.	N
	- to indicate when output exists if a safety hazard could result		N
	- charging mode indicator provided	No battery inside the equipment.	N
56.10	Actuating parts of controls	No actuating parts of controls used.	N
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use		N
	Controls are secured to prevent the movement relative to scale marking (safety related only)		N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N
56.10c	Stops are provided on rotating controls:		N
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard	No such device.	N
	- to prevent damage to wiring		N
56.11	Cord-connected hand-held and foot-operated control devices		N
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g	No cord-connected hand-held or foot-operated control device.	N
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N
	- Foot-operated control devices designed to support the weight of an adult human being		N
	c) Devices not change their setting when inadvertently placed		N
	d) Foot-operated control devices are at least IPX 1		N
	- For surgical use, electrical switching parts are IPX 8		N
	e) Adequate strain relief at the cord entry provided		N

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

18	TABLE: protective earthing				P
Test location		Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks
AC inlet Earth Pin to Enclosure		40	0.4	10 mΩ	2 min
Supplementary information:					

19	TABLE: leakage current					P
Type of leakage current and test condition (including single faults)		Supply voltage (V)	Supply frequency (Hz)	Measured max. value		Remarks
				Before Humidity (µA)	After Humidity (µA)	
Model: ER-191, with D/A inverter: TDK, P/N: TBD319LF-2, LCD panel: NEC, P/N: NL128102BC29						
Figure 16, Earth Leakage						
ER, NC, S1 = 1, S5 = N		264	60	35	37	MD1
ER, NC, S1 = 1, S5 = R		264	60	35	36	MD1
ER, SFC, S1 = 0, S5 = N		264	60	292	292	MD1
ER, SFC, S1 = 0, S5 = R		264	60	295	296	MD1
(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).						

Abbreviations used:

ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA -Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device	A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

20	TABLE: dielectric strength				P
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks	
Before humidity					
A-a1	BI-Basic	250	1707 Vac	Pass	
A-e	DI-double	354	4416 Vac	Pass	
After humidity					
A-a1	BI-Basic	250	1707 Vac	Pass	
A-e	DI-double	354	4416 Vac	Pass	
Supplementary information:					

21	TABLE: mechanical strength	P
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks
Plastic enclosure top/ side/ rear	Force Test: 45N	Pass
Plastic enclosure top/ side/ rear	Impact Test by the impact hammer 0.5 J	Pass
LCD Monitor with base	Drop Test at height: 5 cm	Pass
Supplementary information:		

24	TABLE: - stability	P
Part under test	Test condition	Remarks
LCD Monitor	10° tilt conducted on front, rear and sides	Pass, not overbalance
Supplementary information:		

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

42	TABLE: normal temperature	P

Supply voltage . : 90V, 264V	Test Condition: Normal load
Ambient temperature . : 24.6 ºC, 24.4ºC	

Measuring location	Measured temperature [ºC]				Remarks (Limit)
Model: ER-191, with D/A inverter: TDK, P/N: TBD319LF-2, LCD panel: NEC, P/N: NL128102BC29, Panel placed vertically					
Test Voltage	90V		264V		-
	Measured value at ambient [ºC]	Corrected value at 40 ºC ambient [ºC]	Measured value at ambient [ºC]	Corrected value at 40 ºC ambient [ºC]	
Ambient	24.6	40.0	24.4	40.0	-
Power board T1 coil	70.0	85.4	72.4	88.0	120
Power board T1 core	70.7	86.1	75.1	90.7	120
Main board PWB near U16	62.0	77.4	62.3	77.9	105
Main board PWB near U45	61.6	77.0	61.8	77.4	105
Inverter T2 coil	73.0	88.4	73.1	88.7	105
Inverter T2 core	72.3	87.7	72.3	87.9	105
Enclosure outside near T1	39.8	55.2	40.6	56.2	60
Supplementary information: The tests were conducted under VGA mode. COR - indicates measurements taken using change-of-resistance method					

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection	P

Test type and condition	Part under test	Remarks
To clean with the damp cloth	Unit	PASS
Humidity		
30 ºC, 93%, 168 hrs	Unit	PASS
Supplementary information:		

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

52	TABLE: abnormal operation		P
Test type, condition and clause reference		Observed results	Remarks
Model: ER-191, with D/A inverter: TDK, P/N: TBD319LF-2, LCD panel: NEC, P/N: NL128102BC29, Panel placed vertically			
Ventilation openings blocked		Unit operated normally. No hazard. Temperature data on: T1 coil: 72.2 ºC T1 core: 74.9 ºC Ambient: 26.2 ºC	-
Supplementary information:			

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

56.1	TABLE: lists of critical component parts				P
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
Enclosure (for models GODx7yzMI, GOKx7yzMI)	Bayer	FR2000	Rated V-1 or better, 1.6 mm thick min.	UL 746 (Harmonized with IEC 60707 & IEC 60695-11-10)	UL
-Alternate Use-	Chi Mei	PA-765A	Rated V-1 or better, 1.6 mm thick min.	UL 746 (Harmonized with IEC 60707 & IEC 60695-11-10)	UL
-Alternate Use-	Various	Various	Rated V-1 or better, 1.6 mm thick min.	UL 746 (Harmonized with IEC 60707 & IEC 60695-11-10)	UL
Enclosure (for model: ER-191)	Various	Various	Metal, min. 0.81mm thick	-	-
AC Inlet	Zhang Jia Gang Hua Feng	HF-301	250Vac, 10A	UL 498 VDE 0625 EN 60320	UL, VDE
-Alternate Use-	Solteam	ST-01	250Vac, 10A	UL 498 VDE 0625 EN 60320	UL, VDE
-Alternate Use-	Rich Bay	R-301SN	250Vac, 10A	UL 498 VDE 0625 EN 60320	UL, VDE
Power Switch	Solteam	MR-21	250Vac 10A	UL 1054 VDE 0630 EN 61058	UL, VDE
-Alternate Use-	Zhang Jia Gang Hua Feng	HF-606	250Vac, 12A	UL 1054 VDE 0630 EN 61058	UL, VDE
-Alternate Use-	Light Country	R 19 series	250Vac, 4A	UL 1054 VDE 0630 EN 61058	UL, VDE

IEC 601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
Switching Power Supply	DIVA	DMP8012	I/P: 100-240Vac, 50/60Hz, 1.4-0.7A, Class I O/P: +12V, 7A	IEC 60601-1: 1988+A1+A2	UL, TUV/R (CB Ref. Certificate No.:DE 2-008837)
LCD Panel (see Remark 4 on page 4)	Sharp (Fujitsu)	LQ190E1LW41 (FLC48SXC8V-12)	19 inch, TFT-LCD, 5Vdc, 3.5A max.	-	-
-Alternate Use-	Sharp (Fujitsu)	LQ190E1LW01 (FLC48SXC8V-11)	19 inch, TFT-LCD, 5Vdc, 3.5A max.	-	-
-Alternate Use-	AUO	M190EG01	19 inch, TFT-LCD, 5Vdc, 3A max.	-	-
-Alternate Use-	LG. Philips	LM190E05	19 inch, TFT-LCD, 13.2Vdc, 3A max.	-	-
-Alternate Use-	NEC	NL128102BC29	19 inch, TFT-LCD, 5Vdc, 1.4A max.	-	-
-Alternate Use-	IDTech	ITSX88E	18.1 inch, TFT-LCD, 12Vdc, 46.6W max.	-	-
-Alternate Use-	IDTech	ITSX98E	18.1 inch, TFT-LCD, 12Vdc, 46.6W max.	-	-
D/A Inverter (see Remark 4 on page 4)	Hwa Youn	QF74V5	I/P: 13.2Vdc max., 2.25A max. O/P: 760Vrms, 7.2mA max.	-	-
-Inverter Transformer (T1, T2)	Hwa Youn	EFD15-TF502	105°C	-	-
D/A Inverter (see Remark 4 on page 4)	Hwa Youn	QF171V1	I/P: 13.2Vdc max., 2.75A max. O/P: 750Vrms, 7mA max.	-	-
-Inverter Transformer (T1, T2, T3)	Hwa Youn	EFD15-TF507	105°C	-	-

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
D/A Inverter (see Remark 4 on page 4)	TDK	TBD319LF-1, TBD319LF-2 (two models are identical to each other except for output connector)	I/P: 12.6Vdc max., 3.3A max. O/P: 2000Vrms max., 7.5mA max.	-	-
-Inverter Transformer (T1-T6)	TDK	NIA15/20EM-T68H002	105°C	-	-
D/A Inverter (see Remark 4 on page 4)	Ambit	25L7623	I/P: 12.6Vdc max., 36W max. O/P: 1600Vrms, 6.7mA max.	-	-
-Inverter Transformer (T1-T6)	Xtreme	XT-10370-2033	105°C	-	-
PWB	Lan Circuittech	LCT-M	Rated V-1 or better, 105°C	UL 796 (Harmonized with IEC 60707 & IEC 60695-11-10)	UL
-Alternate Use-	Various	Various	Rated V-1 or better, 105°C	UL 796 (Harmonized with IEC 60707 & IEC 60695-11-10)	UL

[1]) an asterisk indicates a mark which assures the agreed level of surveillance

SUMMARY OF CONTENTS:

The equipment has been tested according to standard IEC 60601-1:1988 Second Edition + A1:1991 + A2:1995.

All applicable tests according to the above specified standard(s) have been carried out.

These tests fulfill the requirements of standard EN45001.

This test report comprises 27 pages of CB Test Report and the following Attachments:

Attachment #	Description	Pages
Appendix 1 to Appendix 5	Photographs	A1 to A5
Appendix 6	Identity Declaration Letter	A6
-	-	-
-	-	-

Note:

Attachments may include Schematics, Components information, Component test Reports, Particular Standard test Reports, Standard test Reports, Information from accompanying documents and similar.

Appendix 1
External front view of LCD Monitor
Model: ER-191

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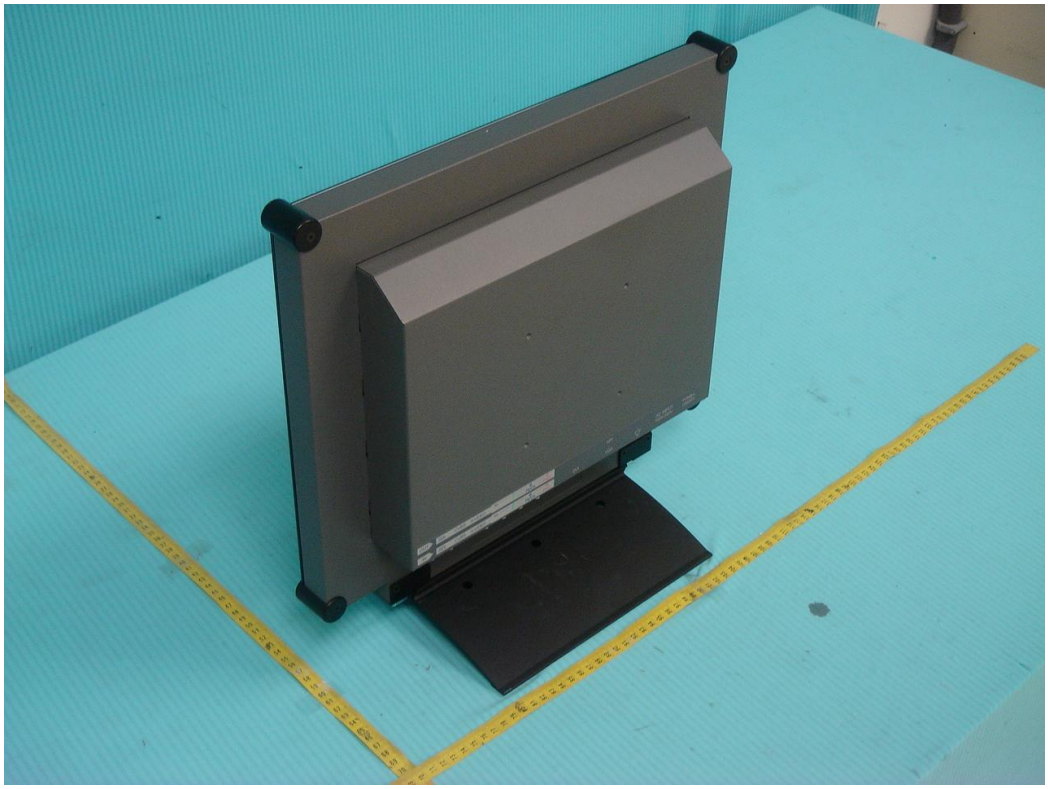
Appendix 2
External rear view of LCD Monitor
Model: ER-191



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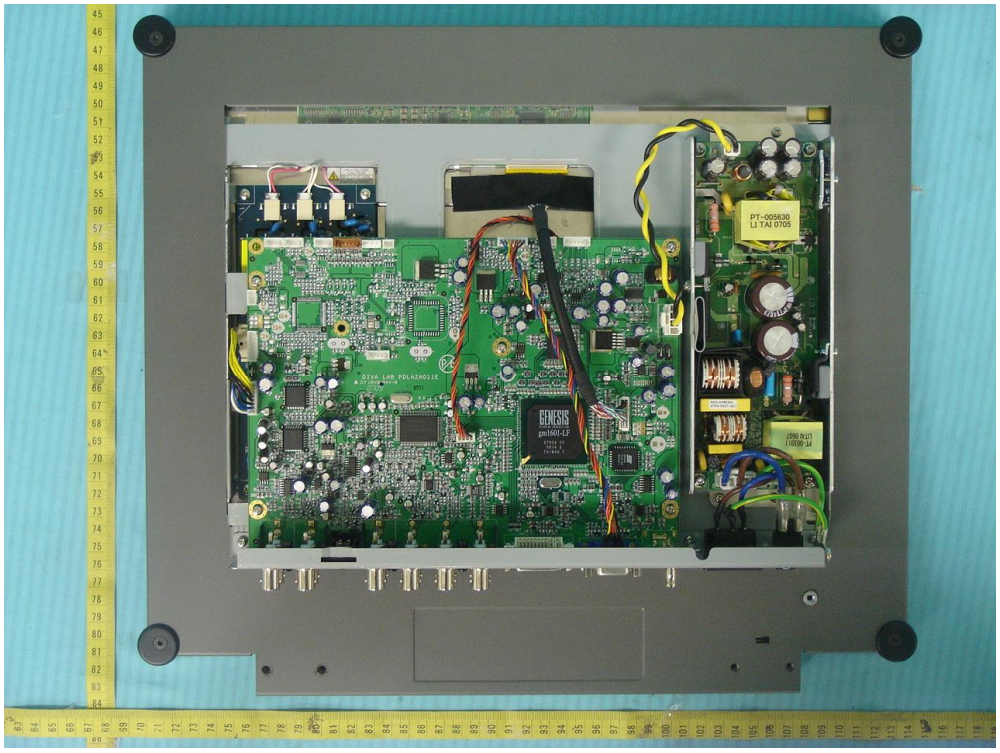
Appendix 3
Internal views of LCD Monitor
Model: ER-191



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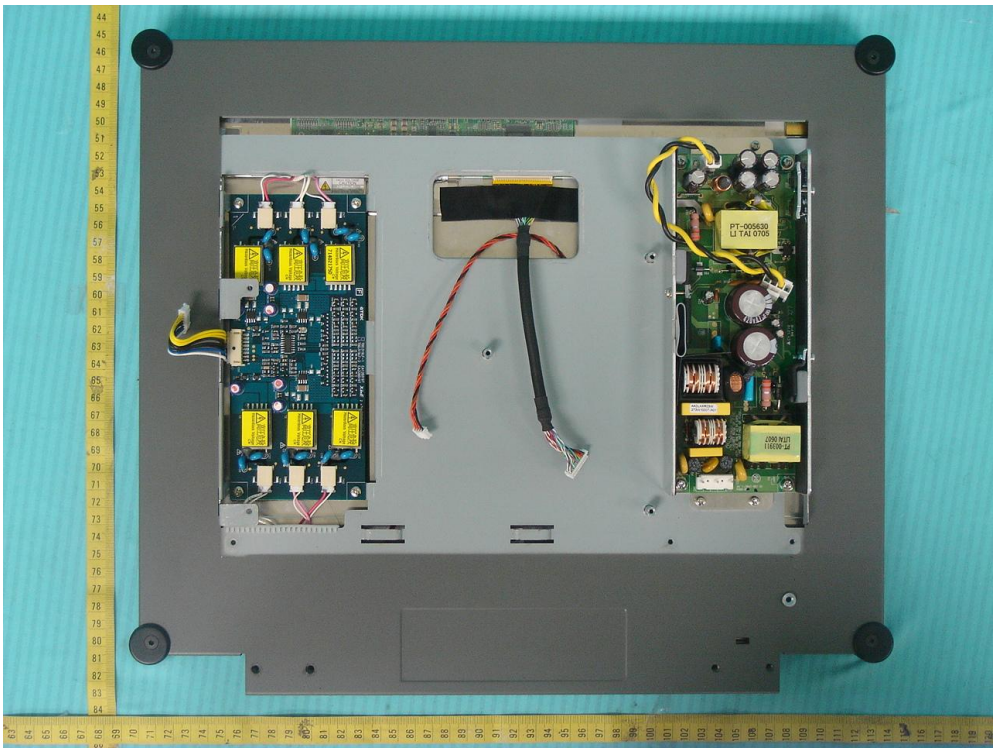

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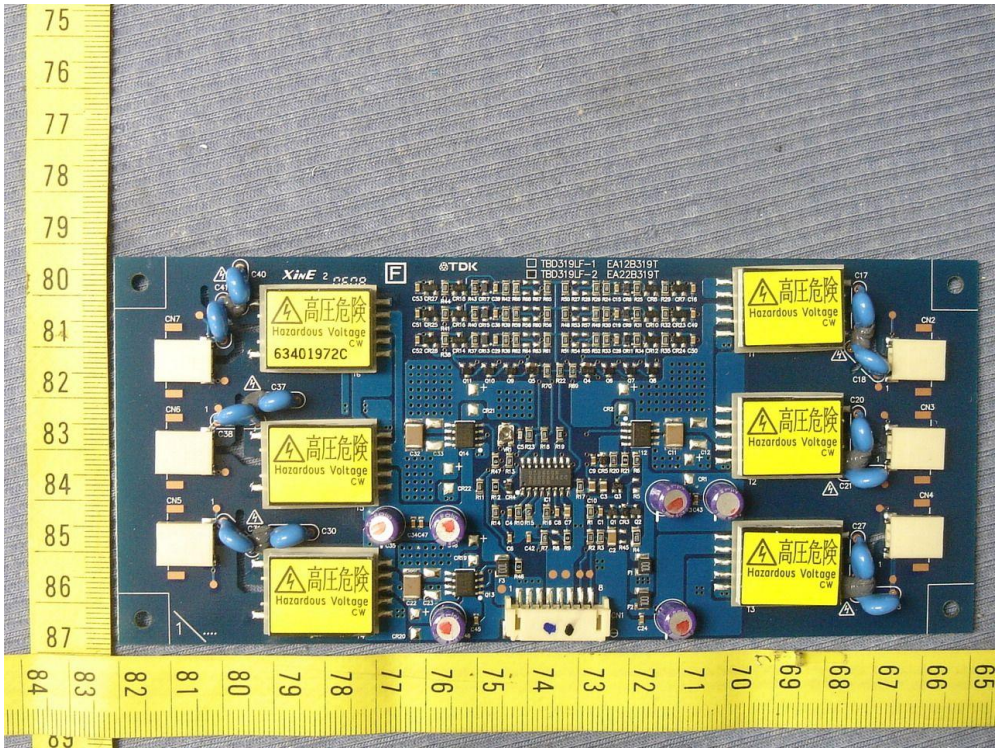
Appendix 4

PWB views of D/A inverter (TDK, P/N: TBD319LF-2) used in LCD Monitor

Model: ER-191



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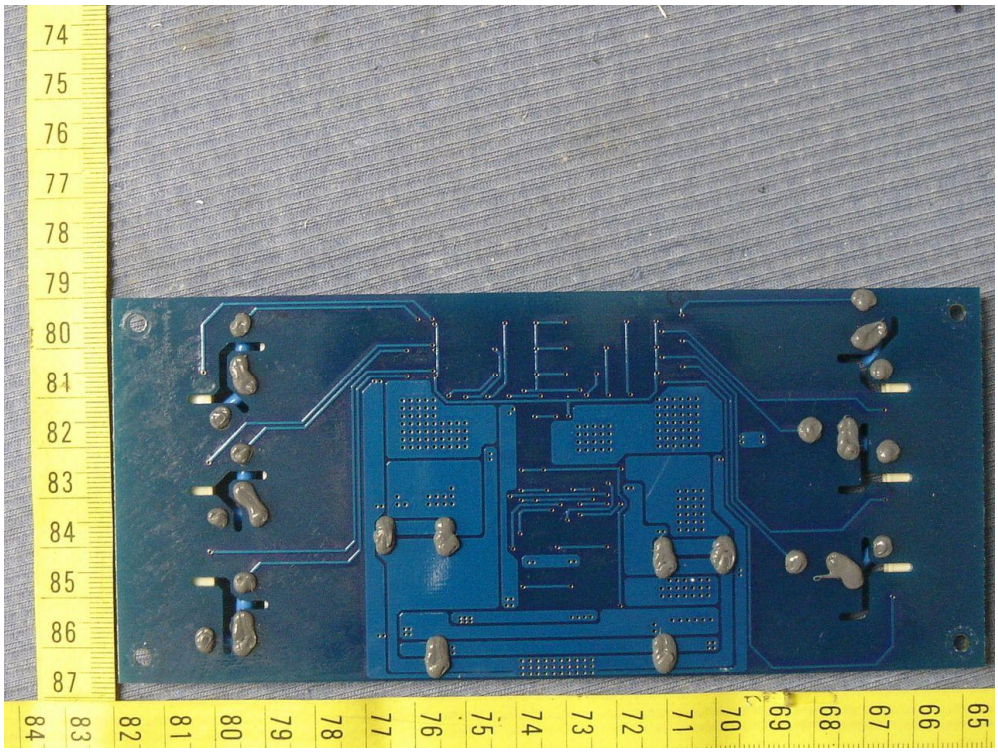

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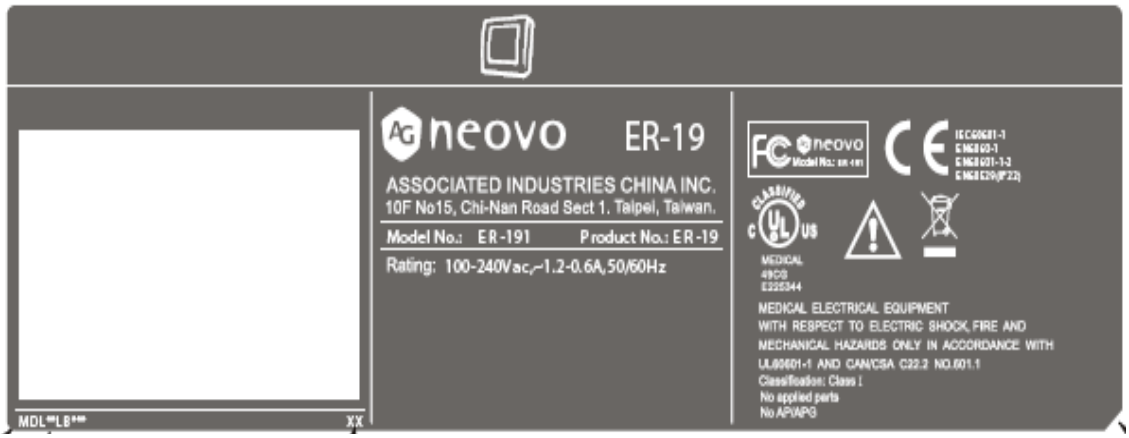
Appendix 5

Product Markings of LCD Monitor

Model: ER-191



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Appendix 6

Letter of Declaration by “DIVA Laboratories Ltd.”

----1 page as attached----

FACSIMILE FORM

鈺緯科技開發股份有限公司
DIVA Laboratories Ltd.

7F-8 , NO,351 , SEC.2 , CHUNG SHAN RD., CHUNG HO ,TAIPEI
HSIEN , TAIWAN , R.O.C.
TEL : 886-2-22268631
FAX : 886-2-22262423

Declaration Letter

Letter Date: 2007/10/17

We, DIVA Laboratories Ltd., have to explain and confirm to our models ER-191.

1. *ER-191 same as GODx7yzMI, GOKx7yzMI (x can be A~Z.) just enclosure different and add IPX2 for this enclosure.*

Best Regards

Signature:

John Liu
Director / R&D Dept